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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,573	08/04/2000	Wilson T. Asfora	00-0050	2575

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EXAMINER	
MAYNARD, JENNIFER J	

ART UNIT	PAPER NUMBER
3763	18

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/633,573	ASFORA, WILSON T.
	Examiner	Art Unit
	Jennifer J Maynard	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,33-35,37-39,42 and 43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12, 33-35, 37-39, 42 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 33-35, 37-39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A), and further in view of Magram (US 5,913,852 A).

Landy et al. discloses an intracranial pressure monitoring probe comprising a tubular portion (i.e. hollow shaft and t-connector) (11, 50) with a threaded portion (26) enabling the tubular portion to extend through all three layers of a patient's skull, the distal end of the tubular portion (i.e. t-connector (50)) provides an interface with a tube (51) allowing fluid communication between the inside of the skull (i.e. subarachnoid space) and a pressure transducer (54), and a wrench or screwdriver (46) with radially extending wings (i.e. handles) (48) provides a mechanism for installing the tubular portion in the patient's skull.

Landy et al. fails to disclose the tubular portion having an integral pair of outwardly extending wings for facilitating finger rotation of the threaded tubular portion.

Miller et al. disclose an apparatus for monitoring local cerebral physiology comprising a subarachnoid bolt (11) defined as a hollow, threaded tubular portion with outwardly extending

wings, which allows the neurosurgeon to torque the bolt into a secure position within the thickness of the cranium, see Column 8, lines 60-63.

It would have been obvious to one having ordinary skill in the art to have modified Landy et al.'s tubular portion with unitary constructed wings associated therewith as taught by Miller et al. so as to eliminate the need for an additional or separate tool to torque the threaded tubular portion into the patient's skull.

Landy et al. in view of Miller et al. fail to disclose the retaining means (50) on the exterior surface of the tubular portion adjacent the distal end for engaging an interior surface of a conduit.

Magram discloses a cannula for draining cerebrospinal fluid from the ventricle of a brain comprising a hollow tubular portion (20, 156, 170) (see Figures 2, 15 and 16) with retaining means (27, 175) (see Column 5, lines 4-16) on the exterior surface thereof for engaging an interior surface of a conduit (152).

It would have been obvious to one having ordinary skill in the art to have modified Landy et al. in view of Miller et al.'s tubular portion with the retaining means (sealing ridges (27, 175)) taught by Magram (see Figures 2 and16) so as to provide a fluid-tight mechanism for connecting the tubular portion to a tubular extension for remotely monitoring intracranial pressure.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A), and further in view of Magram (US 5,913,852 A), as applied to Claims 1-6 above, and further in view of Knute et al. (US 4,903,707 A).

Landy et al. in view of Miller et al. and further in view of Magram disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a drill bit for forming an opening, a stop collar selectively lockable in a position on the drill bit for setting a maximum penetration of the drill into a surface, and a conduit having first and second ends, the first end adapted for connection to the subdural evacuating port device, the second end of the conduit being for connection to a negative source.

Knute et al. discloses a kit for mounting a ventricular catheter assembly comprising a drill bit (81), a stop collar (83) and a conduit (19).

It would have been obvious to one having ordinary skill in the art to have modified the kit disclosed by Landy et al. in view of Miller et al. and further in view of Magram with the drill bit, stop collar and conduit taught by Knute et al., so as to provide means for penetrating the skull of a patient for subsequent placement of the evacuating port device, to limit penetration of the drill bit thus preventing trauma to brain tissue adjacent the skull, and to provide means for draining fluid causing high intracranial pressure.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A), and further in view of Magram (US 5,913,852 A), as applied to Claims 1-6 above, and further in view of Lake (US 3,766,910 A).

Landy et al. in view of Miller et al. and further in view of Magram disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a retractor for spacing sides of an incision in a scalp away from each other.

Lake discloses a disposable delicate tissue retractor comprising a pair of arms (12, 80) each having a proximal ends (no reference numeral; see Figures 2 or 9) joined together to form an apex, each of the arms extending away from the apex such that distal ends (no reference numeral; see Figures 2 and 9) of the arms are spaced from each other, the arms of the retractor forming a substantially V-shaped configuration.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space as taught by Landy et al. in view of Miller et al. and further in view of Magram, by incorporating a retractor such as that which is taught by Lake, so as to allow for exposure of an adequate operative field to aid in proper placement of the subdural evacuating port in the patient's skull.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A), and further in view of Magram (US 5,913,852 A), as applied to Claims 1-6 above, and further in view of Baudino (US 6,110,155 A).

Landy et al. in view of Miller et al. and further in view of Magram disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a negative pressure device for creating a negative pressure condition.

Baudino discloses a catheter (14) for conducting fluid to or from the human body comprising a distal end (18) received in an opening (22) formed in a patient's skull and in a bore (24) formed in the patient's brain tissue (28), a plurality of fluid apertures (32) are provided adjacent the distal end, and a source of negative pressure (no reference numeral; see Column 3,

lines 27-30) can be applied to the proximal end (16) of the catheter to withdraw fluid from the area adjacent to the implanted, distal end.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Landy et al. in view of Miller et al. and further in view of Magram, by incorporating a negative pressure device as disclosed by Baudino, so as to provide means for draining fluid causing high intracranial pressure.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A), further in view of Magram (US 5,913,852 A), and further in view of Baudino (US 6,110,155 A), as applied to Claim 11 above, and further in view of McNeil et al. (US 4,828,546 A).

Landy et al. in view of Miller et al., further in view of Magram, and further in view of Baudino discloses the kit for evacuating a collection of fluid from a subdural space with the exception of the negative pressure device comprising a Jackson-Pratt bulb.

McNeil et al. discloses a bulb evacuator for closed wound suction comprising an interior, a primary opening (20, 21) and a secondary opening (24) providing communication between the interior and an exterior of the bulb, a check valve (23) in communication with the primary opening for resisting exit of fluid from the interior of the bulb to the exterior of the bulb while permitting fluid flow into the interior through the primary opening, and a cap (25) for selectively closing the secondary opening of the bulb.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Landy et al. in view of Miller et al., further

in view of Magram, and further in view of Baudino, by incorporating a bulb evacuator as disclosed by McNeil et al., so as to provide adaptable means for draining fluid causing high intracranial pressure which is characterized by its ease of operation.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A), and further in view of Magram (US 5,913,852 A), as applied to Claims 1-6 above, further in view of Knute et al. (US 4,903,707 A), further in view of Lake (US 3,766,910 A), further in view of Baudino (US 6,110,155 A), and further in view of McNeil et al. (US 4,828,546 A).

Landy et al. in view of Miller et al. and further in view of Magram disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a drill bit for forming an opening, a stop collar selectively lockable in a position on the drill bit for setting a maximum penetration of the drill into a surface, and a conduit having first and second ends, the first end adapted for connection to the subdural evacuating port device, the second end of the conduit being for connection to a negative source.

Knute et al. discloses a kit for mounting a ventricular catheter assembly comprising a drill bit (81), a stop collar (83) and a conduit (19).

It would have been obvious to one having ordinary skill in the art to have modified the kit disclosed by Landy et al. in view of Miller et al. and further in view of Magram with the drill bit, stop collar and conduit taught by Knute et al., so as to provide means for penetrating the skull of a patient for subsequent placement of the evacuating port device, to limit penetration of the drill

bit thus preventing trauma to brain tissue adjacent the skull, and to provide means for draining fluid causing high intracranial pressure.

Landy et al. in view of Miller et al., further in view of Magram, and further in view of Knute et al. disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a retractor for spacing sides of an incision in a scalp away from each other.

Lake discloses a disposable delicate tissue retractor comprising a pair of arms (12, 80) each having a proximal ends (no reference numeral; see Figures 2 or 9) joined together to form an apex, each of the arms extending away from the apex such that distal ends (no reference numeral; see Figures 2 and 9) of the arms are spaced from each other, the arms of the retractor forming a substantially V-shaped configuration.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space as taught by Landy et al. in view of Miller et al. further in view of Magram, and further in view of Knute et al., by incorporating a retractor such as that which is taught by Lake, so as to allow for exposure of an adequate operative field to aid in proper placement of the subdural evacuating port in the patient's skull.

Landy et al. in view of Miller et al., further in view of Magram, further in view of Knute et al., and further in view of Lake disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a negative pressure device for creating a negative pressure condition.

Baudino discloses a catheter (14) for conducting fluid to or from the human body comprising a distal end (18) received in an opening (22) formed in a patient's skull and in a bore (24) formed in the patient's brain tissue (28), a plurality of fluid apertures (32) are provided

adjacent the distal end, and a source of negative pressure (no reference numeral; see Column 3, lines 27-30) can be applied to the proximal end (16) of the catheter to withdraw fluid from the area adjacent to the implanted, distal end.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Landy et al. in view of Miller et al., further in view of Magram, further in view of Knute et al, and further in view of Lake by incorporating a negative pressure device as disclosed by Baudino, so as to provide means for draining fluid causing high intracranial pressure.

Landy et al. in view of Miller et al., further in view of Magram, further in view of Knute et al., further in view of Lake, and further in view of Baudino discloses the kit for evacuating a collection of fluid from a subdural space with the exception of the negative pressure device comprising a Jackson-Pratt bulb.

McNeil et al. discloses a bulb evacuator for closed wound suction comprising an interior, a primary opening (20, 21) and a secondary opening (24) providing communication between the interior and an exterior of the bulb, a check valve (23) in communication with the primary opening for resisting exit of fluid from the interior of the bulb to the exterior of the bulb while permitting fluid flow into the interior through the primary opening, and a cap (25) for selectively closing the secondary opening of the bulb.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Landy et al. in view of Miller et al., further in view of Magram, further in view of Knute et al, further in view of Lake and further in view of Baudino, by incorporating a bulb evacuator as disclosed by McNeil et al., so as to provide

adaptable means for draining fluid causing high intracranial pressure which is characterized by its ease of operation.

Response to Arguments

With respect to Applicant's argument on Page 10, 3rd paragraph through Page 11, 2nd paragraph of the response, which is directed to the incorporation of the sealing ridges (27) of Magram to provide an integral mechanism for connecting the tubular portion to a tubular extension for remotely monitoring intercranial pressure into the device of Landy et al.. Magram's sealing ridges provide a generalized teaching of how to attach a conduit to a connector portion of a tubular portion wherein in a fluid-tight connection is desired. The Examiner contends that Magram's sealing ridges (27) would provide a desired fluid-tight seal while simultaneously acting as a frictional connection for Landy et al.'s tube (51) relative to the tubular portion's t-connector (50) end. Landy et al.'s heavy plastic tube (51) requires some type of sealing means so as to prevent any leakage at the connection site which could undesirably result in inaccurate measurements, thus incorporation of Magram's sealing ridges on the t-connector end of Landy et al.'s tubular portion would provide a sealing means necessary for the desired fluid-tight and frictional connection. Further, Applicant's assertion that Landy's low compliance, heavy plastic tube would be incapable of incorporation of Magram's sealing ridges is unpersuasive in that one of ordinary skill in the art would have found it to be obvious that a low compliance, heavy plastic tube would still exhibit radial flexibility and as such would be able to benefit from the sealing ridges taught by Magram.

With respect to Applicant's argument on Page 11, 2nd paragraph through Page 12, 1st paragraph of the response, which is directed to the incorporation of the lateral extensions (11) of Miller et al. to provide a gripping means into Landy et al's probe. Miller et al.'s lateral extensions provides a surface for applying the necessary torque to thread the bolt into the skull, see Column 8, lines 60-63. The Examiner contends that Miller et al.'s lateral extensions would provide a desired surface for the application of torque by hand, which would obviate the need for an additional tool (i.e. the screw-driver (46)). It should first be noted that the placement of the lateral extensions of Miller et al. need not be bodily incorporated into Landy et al.'s device; that is to say that the span of the wings need not be as exaggerated as shown in Miller et al.'s Figure 3 in order to provide sufficient surface for the application of torque. In any event as shown in Figure 4 of Landy et al., the axial length of cylindrical boss (21) and indented segments (22) is longer than bore (38) in which it is received, therefore it would have been obvious to have mounted the lateral extensions on the portions of the cylindrical boss and/or indented segments which are not received in the bore, so as to avoid the need to lengthen the cylindrical boss or increase the overall length of the tubular portion to accommodate the lateral extensions. In addition, with respect to Applicant's assertion that the increased profile of Landy et al.'s probe as a result of the addition of the lateral extensions would be undesirable, the Examiner contends that any slight additional radial extent caused by the incorporation of lateral extensions would not necessarily significantly increase the bulk of the device, and would not appreciably increase the probability of inadvertent jarring of the device at the implantation site. Furthermore, any increased jarring which might occur would be mitigated by the increased length of Landy et al.'s probe which acts to securely hold it in place, see Column 3, lines 9-17. Further, Applicant's

assertion that shortening the length of the winged handles of Miller et al. would undesirably result in the user being unable to apply sufficient torque is not persuasive in that one skilled in the art would be able to design lateral wings in such a size that would enable the application of manual torque in a sufficient amount without making the device's profile excessively bulky.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 703.305.1356. The examiner can normally be reached on Mondays-Fridays 9:30 AM-5:30 PM; 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703.308.3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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